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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,364	01/13/2004	Steven B. Landau	3506.1000-002	3343
21005 7590 07/19/2007 HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133			EXAMINER CHONG, YONG SOO	
			ART UNIT 1617	PAPER NUMBER
			MAIL DATE 07/19/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/757,364	<b>Applicant(s)</b> LANDAU, STEVEN B.	
	<b>Examiner</b> Yong S. Chong	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) 21-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/4/06</u> | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Status of the Application*

This Office Action is in response to applicant's remarks filed on 7/2/2007.

Claim(s) 1-62 are pending. Claim(s) 21-62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant's election **without traverse** of the restriction requirement in the reply is acknowledged. The requirement is deemed proper and is therefore made FINAL. Claim(s) 1-20 are examined herein insofar as they read on the elected invention and species.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7-16, 21 of copending Application No. 10/757,981; claims 83, 98, 113, 128, 142, 156 of copending

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Application No. 10/846,978. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to a method of treating functional bowel disorders (irritable bowel syndrome) with a compound of formula I, whereas the referenced claims are directed to a method of treating a malady of the gastrointestinal tract with a compound of formula I, where the scope of formula I is identical. Accordingly, it is obvious to treat different forms of IBS, such as diarrhea-predominant and/or constipation-predominant IBS because the genus is taught to be treated with a compound of formula I. Examiner notes that this is a typical genus/species situation. Once a *prima facie* case of obviousness is established, the burden is shifted to the Applicant for objective evidence for nonobviousness. See MPEP 2144.08.

Claims 1-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 64-76 of copending Application No. 11/119,357 and claims 1-20 of copending Application No. 11/441,905. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims disclose a method of treating irritable bowel syndrome by administering a compound of formula I.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-20 of copending Application No. 10/838,789; claims 1-20 of copending Application No. 10/841,317; claims 1-20 of copending Application No. 10/841,318; claims 1-20 of copending Application No. 10/841,319; claims 1-20 of copending Application No. 10/866,593. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham vs John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim(s) 1-20 are rejected under 35 U.S.C. 103(a) as being obvious over Greenbaum et al. (*Digestive Diseases and Sciences*, vol. 32, no. 3, March 1987, 99.257-266, of record) in view of Ninomiya et al. (US Patent 4,695,568, of record).

The instant claims are directed to a method of treating irritable bowel syndrome (IBS) in a subject in need thereof comprising administering a compound of formula I.

Greenbaum et al. teach that anti-depressants, in general, and desipramine, specifically, can be used to treat irritable bowel syndrome. It is also disclosed that IBS can be diarrhea-predominant and/or constipation-predominant (abstract).

However, Greenbaum et al. fail to specifically disclose compounds of formula I.

Ninomiya et al. teach compounds of formula I can be used to treat depression (abstract). A preferred compound is disclosed to be 4-(2-fluorophenyl)-6-methyl-2-

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piperazinyl-thieno[2,3-d]pyrimidine (claim 13). It is also specified that the Ar group of formula I may be a phenyl group, either unsubstituted or substituted with a halogen (claim 1).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to have used a compound of formula I, specifically 4-(2-fluorophenyl)-6-methyl-2-piperazinyl-thieno[2,3-d]pyrimidine, as disclosed by Ninomiya et al. for the treatment of irritable bowel syndrome as disclosed by Greenbaum et al.

A person of ordinary skill in the art would have been motivated to have used a compound of formula I, specifically 4-(2-fluorophenyl)-6-methyl-2-piperazinyl-thieno[2,3-d]pyrimidine, as disclosed by Ninomiya et al. for the treatment of irritable bowel syndrome as disclosed by Greenbaum et al. because: (1) Greenbaum et al. teach that anti-depressants, in general, can be used to treat irritable bowel syndrome; (2) Ninomiya et al. teach that 4-(2-fluorophenyl)-6-methyl-2-piperazinyl-thieno[2,3-d]pyrimidine can be used to treat depression; and (3) because of the reasonable expectation of similar efficacy in substituting one well-known anti-depressant for another. Therefore, the skilled artisan would have had a reasonable expectation of success in treating all forms of irritable bowel syndrome in a patient in need thereof comprising administering 4-(2-fluorophenyl)-6-methyl-2-piperazinyl-thieno[2,3-d]pyrimidine.

Claim(s) 1-10, 12, 14-20 are rejected under 35 U.S.C. 103(a) as being obvious over Bardsley et al. (WO 02/094249 A1, of record) in view of Sanger et al. (WO 94/01095, of record).

The instant claims are directed to a method of treating irritable bowel syndrome (IBS) in a subject in need thereof comprising administering a compound of formula I.

Bardsley et al. teach the use of 4-(2-fluorophenyl)-6-methyl-2-(1-piperazinyl)thieno[2,3-d]pyrimidine for the treatment of pain (abstract).

However, Bardsley et al. fail to teach the nexus between pain and irritable bowel syndrome.

Sanger et al. teach that pain is a symptom of irritable bowel syndrome (pg. 1, line 10).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to have used 4-(2-fluorophenyl)-6-methyl-2-(1-piperazinyl)thieno[2,3-d]pyrimidine as disclosed by Bardsley et al. for the treatment of irritable bowel syndrome as disclosed by Sanger et al.

A person of ordinary skill in the art would have been motivated to have used 4-(2-fluorophenyl)-6-methyl-2-(1-piperazinyl)thieno[2,3-d]pyrimidine as disclosed by Bardsley et al. for the treatment of irritable bowel syndrome as disclosed by Sanger et al. because: (1) Bardsley et al. teach the use of 4-(2-fluorophenyl)-6-methyl-2-(1-piperazinyl)thieno[2,3-d]pyrimidine for the treatment of pain; (2) Sanger et al. teach that pain is a symptom of irritable bowel syndrome; and (3) since treating a symptom of a disease is considered treating the disease itself, treating pain is considered treating



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irritable bowel syndrome. Therefore, the skilled artisan would have had a reasonable expectation of success in treating irritable bowel syndrome by administering 4-(2-fluorophenyl)-6-methyl-2-(1-piperazinyl)thieno[2,3-d]pyrimidine.

Accordingly, it is obvious to treat different forms of IBS, such as diarrhea-predominant and/or constipation-predominant IBS because the genus is taught to be treated with 4-(2-fluorophenyl)-6-methyl-2-(1-piperazinyl)thieno[2,3-d]pyrimidine. Examiner notes that this is a typical genus/species situation. Once a *prima facie* case of obviousness is established, the burden is shifted to the Applicant for objective evidence for nonobviousness. See MPEP 2144.08.

### ***Conclusion***

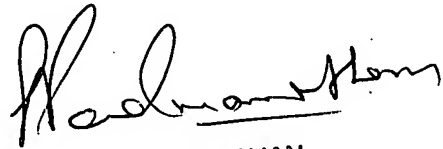
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC



SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER